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PATENT
Docket No. 275.0009 0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	MUNN et al.	Group Art Unit:	1645
Serial No.:	10/780,150	Examiner:	Unassigned
Confirmation No.:	1273		
Filed:	February 17, 2004		

For: REGULATION OF T CELL-MEDIATED IMMUNITY BY D ISOMERS OF INHIBITORS OF INDOLEAMINE-2,3-DIOXYGENASE

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. As this patent application was filed after June 30, 2003, copies of the U.S. patents and U.S. patent application publications listed on the attached 1449 form(s) have not been submitted). Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants also wish to bring to the Examiner's attention the following pending U.S. Applications, as well as any documents, Office Actions that may include rejections of similar claims, and any provisional U.S. patent applications referenced in the pending U.S. applications or in their file wrappers. A copy of each of the below-listed pending U.S. Patent Applications is provided herewith.

List of Pending Non-Published U.S. Patent Applications

Applicant(s)	Application Number	Filing Date	Serial No. of Provisional Application to which listed Application claims priority
MUNN et al.	10/780,797	02/17/04	60/538,647 and 60/459,489

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of Sept, 2004.

Sandra J. Truhart

Name: Sandra J. Truhart

September 17, 2004
Date

NAJ/sjt

Respectfully submitted for
MUNN et al.
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612)305-1220
Facsimile: (612)305-1228
Customer Number 26813

By: Nancy A. Johnson
Nancy A. Johnson
Reg. No. 47,266
Direct Dial (612)305-4723

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We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X Small entity status is entitled to be asserted in the above-identified application.
X An itemized return postcard.
___ A Petition for Extension of Time for _ month(s) and a check in the amount of $_ for the required fee.
X An Information Disclosure Statement (2 pgs); copy of 1 application; 1449 forms (14 pgs); and copies of 149 documents cited on the 1449 forms.
___ A check in the amount of $_, representing ___.
___ A certified copy of a _ application, Serial No. _, filed _____, the right of priority of which is claimed under 35 U.S.C. §119.
___ Other:
___ Amendment ___ No Additional fee is required. ___ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $9 =	
Independent Claims				x $43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $145 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of September, 2004.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: Nancy A. Johnson
Name: Nancy A. Johnson
Reg. No.: 47,266
Direct Dial: 612-305-4723
Facsimile: 612-305-1228

(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)

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	Applicant(s): MUNN et al.	Confirmation No.: 1273
	Application Filing Date: 02/17/04	Group: 1645
	Information Disclosure Statement mailed:	

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,478,556	12/26/95	Elliott et al.			
		5,837,231	11/17/98	Low et al.			
		5,861,159	01/19/99	Pardoll et al.			
		6,251,399	06/26/01	Diamond et al.			
		6,395,876 B1	05/28/02	Munn et al.			
		6,451,840	09/17/02	Munn et al.			
		6,482,416	11/19/02	Munn et al.			
		2002 0155104 A1	10/24/02	Munn et al.			
		2002 0114784 A1	08/22/02	Li et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	✔	99/29852	06/17/99	WO				
	✔	99/29310	06/17/99	WO				

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
	✔	Alberti-Giani, "Regulation of the Kynurenine Metabolic Pathway by Interferon-γ in Murine Cloned Macrophages and Microglial Cells," *J. Neurochem*, 1996;66:996-1004.
	✔	Alexander et al., "Indoleamine 2,3-Dioxygenase Expression in Transplanted NOD Islets Prolongs Graft Survival After Adoptive Transfer of Diabetogenic Splenocytes," *Diabetes*, 2002;51:356-365.
	✔	Almand et al., "Clinical Significance of Defective Dendritic Cell Differentiation in Cancer," *Clin. Cancer Res.*, 2000;6:1755-1766.
	✔	Asselin-Paturel et al., "Mouse type I IFN-producing cells are immature APCs with plasmacytoid morphology," *Nat. Immunol.*, 2001;2:1144-1150.

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	✔	Aune et al., "Inhibition of Tumor Cell Growth by Interferon-γ Is Mediated by Two Distinct Mechanisms Dependent upon Oxygen Tension: Induction of Tryptophan Degradation and Depletion of Intracellular Nicotinamide Adenine Dinucleotide," *J Clin Invest*, 1989;84:863-875.
	✔	Azuma, et al., "B70 antigen is a second ligand for CTLA-4 and CD28," *Nature* 1993;366:76-79.
	✔	Ben-Efraim, "Immunomodulating Anticancer Alkylating Drugs: Targets and Mechanisms of Activity," *Current Drug Targets*, 2001;2:197-212.
	✔	Benson et al., "T-cell activation and receptor downmodulation precede deletion induced by mucosally administered antigen," *J. Clin. Invest.*, 2000;106:1031-1038.
	✔	Bjorck et al., "Cutting Edge: CD19+ Pro-B Cells Can Give Rise to Dendritic Cells *In Vitro*," *J. Immunol.*, 1998;161:5795-5799.
	✔	Borrello et al., "A Universal Granulocyte-Macrophage Colony-Stimulating Factor-Producing Bystander Cell Line for Use in the Formulation of Autologous Tumor Cell-Based Vaccine," *Hum. Gene. Ther.*, 1999;10:1983-1991.
	✔	Bronte et al., "Unopposed Production of Granulocyte-Macrophage Colony-Stimulating Factor by Tumors Inhibits CD8+ T Cell Responses by Dysregulating Antigen-Presenting Cell Maturation," *J. Immunol.*, 1999;162:5728-5737.
	✔	Carlin et al., "Intrferon-Induced Indoleamine 2,3-Dioxygenase Activity in Human Mononuclear Phagocytes," *J. Leuk. Biol.* 1989;45:29-34.
	✔	Cella et al., "Plasmacytoid monocytes migrate to inflamed lymph nodes and produce large amounts of type I interferon," *Nat. Med.*, 1999;5:919-923.
	✔	Chambers, "The expanding world of co-stimulation: the two-signal model revisited," *Trend Immunol.* 2001;22:217-223.
	✔	Chen et al., "The Role of Tumor Necrosis Factor α in Modulating the Quantity of Peripheral Blood-Derived, Cytokine-Driven Human Dendritic Cells and Its Role in Enhancing the Quality of Dendritic Cell Function in Presenting Soluble Antigens to CD4+ T Cells in Vitro," *Blood*, 1998;91:4652-4661.

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	✔	Chon, "Cooperative Role of Interferon Regulatory Factor 1 and p91 (STAT1) Response Elements in Interferon-γ-inducible Expression of Human Indoleamine 2,3-Dioxygenase Gene," *J Biol Chem*, 1996;271:17247-17252.
	✔	Cochran et al., "Sentinel Lymph Nodes Show Profound Downregulation of Antigen-Presenting Cells of the Pracortex: Implications for Tumor Biology and Treatment," *Mod. Pathol.*, 2001;14:604-608.
	✔	Colasante et al., "Role of Cytokines in Distribution and Differentiation of Dendritic Cell/Langerhans' Cell Lineage in Human Primary Carcinomas of the Lung," *Hum. Pathol.*, 1995;26:866-872.
	✔	Corbett et al., "Response of Transplantable Tumors of Mice to Anthracenedione Derivatives Alone and in Combination with Clinically Useful Agents," *Cancer Treatment Reports*, 1982;66:1187-1200.
	✔	Corcoran et al.,"The lumphoid Past of Mouse Plasmacytoid Cells and Thymic Dendritic Cells," *J. of Immunology*, 2003;170:4926-4932.
	✔	Cuenca et al., "Extra-Lymphatic Solid Tumor Growth Is Not Immunologically Ignored and Results in Early Induction of Antigen-Specific T-Cell Anergy: Dominant Role of Cross-Tolerance to Tumor Antigens," *Cancer Res.*, 2003;63:9007-9015.
	✔	Curreli et al., "Human Primary CD4+ T Cells Activated in the Presence of IFN-α2b Express Functional Indoleamine 2,3-Dioxygenase," *J. Interferon Cytokine Res.*, 2001;21:431-437.
	✔	Dai et al., "Molecular Clong, sequencing and expression of human interferon-gamma-inducible indoleamine 2,3-dioxygenase cDNA," *Biochem. Biophys. Res. Commun.*, 1990;168:1-8 GenBank Accession Number M34455.
	✔	Daubener, "Establishment of T-helper type 1- and T-helper type 2-like human *Toxoplasma* antigen-specific T-cell clones," *Immunol.* 1995;86:79-84.
	✔	Daubener, et al., "Anti-parasitic effector mechanisms in human brain tumor cells: role of interferon-γ and tumor necrosis factor-α," *Eur. J. Immunol.* 1996;26:487-492.
	✔	Dranoff, "GM-CSF-based cancer vaccines," *Immunol. Rev.* 2002;188:147-154.

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	✔	Dranoff et al., "Vaccination with irradiated tumor cells engineered to secrete murine granulocyte-macrophage colony-stimulating factor stimulates potent, specific, and long-lasting anti-tumor immunity," *Proc. Natl. Acad. Sci.* USA, 1993;90:3539-3543.
	✔	Dudley et al., "Cancer Regression and Autoimmunity in Patients After Clonal Repopulation with Antitumor Lymphocytes," *Science*, 2002;298:850-854. Supplemental On-line Material can be retrieved from www.sciencemag.org/cqi/content/full/1076514/DC1
	✔	Dzionek et al., "BDCA-2, BDCA-3, and BDCA-4: Three Markers for Distinct Subsets of Dendritic Cells in Human Peripheral Blood," *J Immunol.*, 2000;165:6037-6046.
	✔	Fallarino et al., "Functional expression of indoleamine 2,3-dioxygenase by murine CD8α+ dendritic cells," *Int. Immunol.*, 2002;14:65-68.
	✔	Fallarino et al., "Modulation of tryptophan catabolism by regulator T cells," *Nat. Immunol.*, 2003;4:1206-1212. Epub 2003, Oct. 26.
	✔	Fearon et al., The Instructive Role of Innate Immunity in the Acquired Immune Response," *Science* 1996;272:50-54.
	✔	Fearon et al., "Regulation of B Lymphocyte Responses to Foreign and Self-Antigens by the CD19/CD21 Complex," *Ann. Rev. Immunol.*, 2000;18:393-422.
	✔	Feng et al., "Interferon γ-resistant mutants are defective in the induction of indoleamine 2,3-dioxygenase," *Proc. Natl. Acad. Sci.*, USA, 1989;86:7144-7148.
	✔	Friberg et al., "Indoleamine 2,3-dioxygenase contributes to tumor cell evasion of T cell mediated rejection," *Intl J of Cancer*, 2002;101:151-155.
	✔	Grant et al., "Induction of Indolamine 2,3-Dioxygenase in Primary Human Macrophages by Human Immunodeficiency Virus Type 1 Is Strain Dependent," *J. Virol.*, 2000;74:4110-4115.
	✔	Grohmann et al., "IFN-γ Inhibits Presentation of a Tumor/Self Peptide by CD8α$^-$ Dendritic Cells Via Potentiation of the CD8α$^+$ Subset[1]," *J. Immunol.*, 2000;165:1357-1363.
	✔	Grohmann et al., "CD40 Ligation Ablates the Tolerogenic Potential of Lymphoid Dendritic Cells[1]," *J. Immunol.* 2001;166:277-283.

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	✔	Grohmann et al., "IL-6 Inhibits the Tolerogenic Function of CD8α^+ Dendritic Cells expressing Indoleamine 2,3-Dioxygenase[1]," *J. Immunol.* 2001;167:708-714.
	✔	Grohmann et al., "CTLA-4-Ig regulates tryptophan catabolism *in vivo*," *Nature Immunology* 2002;3:1097-1101.
	✔	Grohmann et al., "CTLA-4-Ig regulates tryptophan catabolism in vivo," 2002 Nature Publishing Group. Available at http://www.nature.com/natureimmunology Advance online publication. pp. 1-5
	✔	Grohmann et al., "Tolerance, Dcs and tryptophan: much ado about IDO," *Trends in Immunology* 2003;24:242-248.
	✔	Grohmann et al., "A Defect in Tryptophan Catabolism Impairs Tolerance in Nonobese Diabetic Mice," *J. Exp. Med.* 2003;198:153-160.
	✔	Gupta, "Antiparasitic and Antiproliferative Effects of Indoleamine 2,3-Dioxygenase Enzyme Expression in Human Fibroblasts," *Infect. Immun.* 1994; 62:2277-2284.
	✔	Hashimoto et al., "Determination of free amino acid enantiomers in rat brain and serum by high-performance liquid chromatography after derivatization with N-*tert.*-butyloxycarbonyl-L-cysteine and *o*-phthaldialdehyde," *J. Chromatography* 1992;582:41-48.
	✔	Hawiger et al., "Dendritic Cells Induce Peripheral T Cell Unresponsiveness Under Steady State Conditions in Vivo," *J. Exp. Med.*, 2001;194:769-779.
	✔	Huang et al., "Role of Bone Marrow-Derived Cells in Presenting MHC Class I-Restricted Tumor Antigens," *Science,* 1994;264:961-965.
	✔	Hwu et al., "Indoleamine 2,3-Dioxygenase Production by Human Dendritic Cells Results in the Inhibition of T Cell Proliferation," *J. Immunol.* 2000;164:3596-3599.
	✔	Izon et al., "A Common Pathway for Dendritic Cell and Early B Cell Development," *J. Immunol.*, 2001;167:1387-1392.
	✔	Jonuleit et al., "Pro-inflammatory cytokines and prostaglandins induce maturation of potent immunostimulatory dendritic cells under fetal calf serum-free conditions," *Eur. J. Immunol.*, 1997;27:3135-3142.

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	✔	Kamimura et al., "Localization and Developmental Change of Indoleamine 2,3-Dioxygenase Activity in the Human Placenta," *Acta. Med.* Okayama, 1991;45:135-139.
	✔	Karsunky et al., "Flt3 Ligand Regulates Dendritic Cell Development from $Flt3^+$ Lymphoid and Myeloid-committed Progenitors to $Flt3^+$ Dendritic Cells In Vivo," *J. Exp. Med.*, 2003;198:305.
	✔	Koide, "The Signal Transduction Mechanism Responsible for Gamma Interferon-Induced Indoleamine 2,3-Dioxygenase Gene Expression," *Infect. Immun.* 1994;62:948-955.
	✔	Konan, "Importance of the Two Interferon-stimulated Response Element (ISRE) Sequences in the Regulation of the Human Indoleamine 2,3-Dioxygenase Gene," *J Biol Chem*, 1996;271:19140-19145.
	✔	Konieczny et al., "IFN-γ Is Critical for Long-Term Allograft Survival Induced by Blocking the CD28 and CD40 Ligand T Cell Costimulation Pathways[1]," *J. Immunol.*, 1998;160:2059.
	✔	Kotera et al., "Comparative Analysis of Necrotic and Apoptotic Tumor Cells As a Source of Antigen(s) in Dendritic Cell-based Immunization[1]," *Cancer Research* 2001;61(22):8105-8109.
	✔	Kudo et al., "Human placental indoleamine 2,3-dioxygenase: cellular localization and characterization of an enzyme preventing fetal rejection," *Biochem. Biophys. Acta*, 2000;1500:119-124.
	✔	Lee et al., "Pattern of Recruitment of Immunoregulatory Antigen-Presenting Cells in Malignant Melanoma," *Laboratory Investigation*, 2003;83:1457-1466.
	✔	Lee et al., "Tryptophan deprivation sensitizes activated T cells to apoptosis prior to cell division," *Immunology* 2002;107:452-460.
	✔	Logan et al., "HeLa cells cocultured with peripheral blood lymphocytes acquire an immuno-inhibitory phenotype through up-regulation of indoleamine 2,3-dioxygenase activity," *Immunol.*, 2002;105:478.
	✔	Mackensen, et al., "Delineation of the Dendritic Cell Lineage by Generating Large Numbers of Birbeck Granule-Positive Langerhans Cells from Human Peripheral Blood Progenitor Cells in Vitro," *Blood* 1995;86:2699-2707.

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	✔	Manegold et al., "Gemcitabine in non-small cell lung cancer (NSCLC)", *Invest New Drugs*. 2000;18(1):29-42.
	✔	Martin et al., "Characterization of a new subpopulation of mouse CD8α^+ B220$^+$ dendritic cells endowed with type 1 interferon production capacity and tolerogenic potential," *Blood*, 2002;100:383-390.
	✔	Mattei et al., "Expression of Cytokine/Growth Factors and Their Receptors in Human Melanoma and Melanocytes," *Int. J. Cancer*, 1994;56:853-857.
	✔	McIlroy et al., "Investigation of human spleen dendritic cell phenotype and distribution reveals evidence of in vivo actibation in a subset of organ donors," *Blood*, 2001; 97:3470-3477.
	✔	Medawar, "Some Immunological and Endocrinological Problems Raised by the Evolution of Viviparity in Vertebrates," *Symp. Soc. Exp. Biol.* 1953;7:320-388.
	✔	Mellor et al., "Cells expressing indoleamine 2,3-dioxygenase inhibit T cell responses," *J Immunol.*, 2002;168:3771-3776.
	✔	Mellor et al., "Cutting Edge: Induced indoleamine 2,3 dioxygenase expression in dendritic cell subsets suppresses T cell clonal expansion," *J Immunol*, 2003;171:1652-1655.
	✔	Mellor et al., "Prevention of T cell-driven complement activation and inflammation by Tryptophan catabolism during pregnancy," *Nature Immunol* 2001;2:64-68.
	✔	Mellor et al., "Indoleamine 2,3-dioxygenase, immunosuppression and pregnancy," *J. Reprod. Immunol.* 2002;57:143-150.
	✔	Mellor et al., "Tryptophan catabolism and regulation of adaptive immunity," J. Immunol. 2003;170:5809-5813.
	✔	Mellor et al., "Tryptophan catabolism and T cell tolerance: immunosuppression by starvation?," *Immunol. Today* 1999;20:469-473.
	✔	Miki et al., "Blockade of Tryptophan Catabolism Prevents Spontaneous Tolerogenicity of Liver Allografts" *Transplantation Proceedings* 2001;33:129-130.
	✔	Mikkola et al., "Reversion of B Cell Commitment Upon Loss of Pax5 Expression," *Science*, 2002;297:110-113.

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	✔	Moffett et al., "Antibodies to quinolinic acid and the determination of its cellular distribution within the rat immune system," *Cell Tissue Res*, 1994;278:461-469.
	✔	Mondino, et al., "The anatomy of T-cell activation and tolerance," *Proc. Natl. Acad. Sci* USA 1996;93:2245-2252.
	✔	Morahan, et al., In: Heppner GA, Fulton AM, eds. *Macrophages and Cancer*, Boca Raton, FL: CRC Press 1988:1-25.
	✔	Moser, "Dendritic Cells in Immunity and Tolerance - Do They Display Opposite Functions?" *Immunity*, 2003;19:5-8.
	✔	Munn, "Cytokine Regulation of Human Monocyte Differentiation in Vitro: The Tumor-Cytotoxic Phenotype Induced by Macrophage Colony-Stimulating Factor is Developmentally Regulated by γ-Interferon," *Cancer Res.* 1993;53:2603-2613.
	✔	Munn et al., "Selective Activation-Induced Apoptosis of Peripheral T Cells Imposed by Macrophages," *J. Immunol.*, 1996;156:523-532.
	✔	Munn et al., "Prevention of Allogeneic Fetal Rejection by Tryptophan Catabolism," *Science* 1998; 281:1191-1193.
	✔	Munn et al., "Inhibition of T cell proliferation by macrophage tryptophan catabolism,", *J Exp Med*, 1999;189:1363-1372.
	✔	Munn et al., "Potential regulatory function of human dendritic cells expressing indoleamine 2,3-dioxygenase," *Science*, 2002;297:1867-1870. Supporting On-Line Material available at www.sciencemag.org/cgi/data/297/5588/1867/DC1/1
	✔	Munn, "Selecting the right dentritic cell subset," Lecture Presented January 31, 2003 at Tandem BMT Meetings at Keystone. January 30-February 3, 2003, 57 pages.
	✔	Munn et al., "Expression of indoleamine 2,3-dioxygenase by plasmacytoid dendritic cells in tumor-draining lymph nodes," *J. Clin Invest* 2004;114:280-290.
	✔	Munn et al., "IDO and tolerance to tumors," *Trends Molec Med.* 2004;10:15-18.
	✔	Musso, "Interleukin-r Inhibits Indoleamine 2,3-Dioxygenase Expression in Human Monocytes," *Blood* 1994; 83:1408-1411.

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	✔	Nossal, "Negative Selection of Lymphocytes," *Cell* 1994;76:229-239.
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	✔	Reddy et al., "A Monocyte Conditioned Medium Is More Effective Than Defined Cytokines in Mediating the Terminal Maturation of Human Dendritic Cells," *Blood,* 1997:90:3640-3646.
	✔	Report on the Rare Diseases Research Activities at the National Institutes of Health FY 2003. NSC Number 721782 (Group 2A, pg. 13). 17 pages. Retrieved from the Internet on 07/29/04 at http://rarediseases.info.nih.gov/html/reports/fy2003/nci.html
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